



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,902	02/13/2002	Gary N. Cherr	309T-300410US	1913

22798 7590 12/28/2006
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER

CHONG, YONG SOO

ART UNIT	PAPER NUMBER
----------	--------------

1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/076,902	Applicant(s) CHERR ET AL.	
	Examiner Yong S. Chong	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35, 37-39, 41-43, 45-49, 51 and 53-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-34, 38, 45-48 and 53-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35, 37, 39, 41-43, 49, 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/2006 has been entered.

Claim(s) 36, 40, 44, 50, 52 have been cancelled. Claim(s) 1-34, 38, 45-48, 53-55 have been withdrawn. Claim(s) 1-35, 37-39, 41-43, 45-49, 51, 53-55 are pending. Claim(s) 35, 37, 39, 41-43, 49, 51 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 35, 37, 39, 41-43, 49, 51 are rejected under 35 U.S.C. 103(a) as being obvious over Salinas et al. (In abstracts, 21st Annual Meeting of the Society of Environmental Toxicology and Chemistry, Nashville, TN "Identification of cell surface domains for lignosulfonic acids derived from pulp mill effluent," Nov 2000) in view of Ward et al. (US Patent 4,185,097) and Anderson et al. (US Patent 6,063,773).

The instant claims are directed to a composition comprising at least one sulfonated compound, an excipient, spermicide, and a sperm from a mammal, human, canine, feline, or rodent.

Salinas et al. teach that breakdown products from lignin, specifically lignosulfonic acid (LSA), inhibit fertilization by binding to sperm domain head, thus preventing

acrosome reaction. LSA also has the ability to inhibit the infectivity of the HIV virus (abstract). It is noted that lignin is known from a woody plant (see definition of lignin, specifically its ordinary and customary meaning provided by the American Heritage Dictionary, Second College Edition, 1982, pg. 730, of record; see also US Patent 5,698,524 abstract, of record).

Ward et al. teach that lignosulfonate (LSA) is useful for combating Herpes simplex viruses in animals (abstract).

Anderson et al. teach that known spermicide, nonoxynol-9, is known to be useful in a pharmaceutical composition for contraception or inhibiting fertilization (col. 1, lines 23-32. Suitable carriers and diluents may be combined with nonoxynol-9 (col. 3, lines 16-19). Anderson et al. also disclose that sexually transmitted diseases such as AIDS caused by HIV present a serious health risk. Therefore, it is important to develop a method, which provides protection against infectious microbes and unwanted pregnancies (col. 1, lines 38-44) in woman.

However, Salinas et al., Ward et al., and Anderson et al. fail to disclose a specific composition comprising LSA, spermicide, and sperm from mammals.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine LSA and nonoxynol-9 with sperm from a mammal.

A person of ordinary skill in the art would have been motivated to make this combination because: (1) both Salinas et al. and Anderson et al. teach the inhibition of fertilization of LSA and nonoxynol-9, respectively, thus making the case for the art

Art Unit: 1617

equivalence between the two compounds; (2) both Salinas et al. and Ward et al. teach that LSA combats sexually transmitted diseases such as HIV and Herpes, which is corroborated by the fact that Anderson et al. discloses the importance of protecting against sexually transmitted diseases when using contraception such as nonoxynol-9. Thus, it would be obvious to administer this contraceptive composition, comprising LSA and nonoxynol-9, to the sperm of mammals because of the reasonable expectancy of successfully inhibiting fertilization and protecting against sexually transmitted diseases.

Response to Arguments

Applicant argues that there is no motivation to combine Salinas with the other references because the teaching of Salinas is actually narrower than that put forth by the previous Office Action. Salinas teach inhibition of fertilization by LSA by binding to sperm heads, but only for sea urchins and not in mammalian systems as is taught by Ward and Anderson. Sea urchins and mammalian sperm are strikingly different in their composition and their maturation as well as the different environmental factors, such as pH levels, temperatures, salt concentrations.

This is not persuasive because Salinas, Ward, and Anderson give the general teaching that LSA and nonoxynol-9 inhibit fertilization. Although the mechanism is different as a result of differences in sperm, the end goal of inhibiting fertilization is achieved. Applicant has not provided definitive proof that LSA would not bind to the mammalian sperm head. Thus, the motivation to combine both LSA and nonoxynol-9 is because the skilled artisan would have had a reasonable expectation of success in

inhibiting fertilization. The arguments directed to different environmental factors are not persuasive because there are many aquatic mammals (e.g. porpoises, dolphins, whales) that share the same pH level, temperature, and salt concentrations as echinoderms.

Applicant argues that mammalian eggs comprise a thick glycoprotein layer (zona pellucida) while echinoderms do not. Since mammalian sperm undergo capacitation wherein the surface of the sperm is removed/altered, those of skill in the art would expect that the LSA bound to the sperm head would likely be removed or altered as well.

This is not persuasive because although capacitation involves the surface of the sperm to be altered, this does not inhibit or change LSA binding to the sperm head. There is no mention in any of the supplied references (Yudin and Knobil) that capacitation will inhibit LSA binding or the function of spermicides for that matter. In fact, capacitation will assist in inhibiting fertilization because once capacitation has taken place, acrosome reaction is allowed to occur, according to Yudin. Once the sperm surface coat is removed, LSA can more effectively inhibit fertilization by binding to the exposed acrosome.

The arguments directed to the Salinas dissertation, dated 2004, will not be considered since it was available to the public after the filing of the instant invention.

Applicant argues that LSA and spermicides are roughly lumped together and that their characterization is too broad. Applicant argues that the purposes for LSA and nonoxynol-9 are not the same as their mechanisms differ. This is not persuasive

because both are taught to inhibit fertilization. Examiner does not view this end result as overly broad or too general.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER